## Section A: Clinical Milestones and Events

Clinical Milestones and Events Data Collection Table

| Milestone or Event | Yes/No/Unknown | Date(s) List all, as applicable (DD/M M/YYYY) |
| --- | --- | --- |
| Noninvasive ventilation (NIV) utilized | Yes  No  Unknown | // |
| Loss of speech | Yes  No  Unknown | // |
| Loss of ambulation | Yes  No  Unknown | // |
| Percutaneous endoscopic gastrostomy /Feeding tube placement | Yes  No  Unknown | // |
| Trachestomy performed | Yes  No  Unknown | // |
| Death | \*Yes  No  Unknown | \*If participant/ subject died, complete Death CRF |

## Section B: Clinical Events - Falls

We would like you to keep a diary about any falls that you might have. Please mark the appropriate box(es) every day to indicate when you have not fallen or when you have almost fallen and/or when you have had an actual fall. Please record the number of falls and near falls you experience in the space provided on the daily calendar. If you have a fall that requires medical attention, please remember to tell us about this at your next study visit.

Clinical Events and Falls Data Collection Grid

| **Sunday** | **Monday** | **Tuesday** | **Wednesday** | **Thursday** | **Friday** | **Saturday** |
| --- | --- | --- | --- | --- | --- | --- |
| Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: |
| Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: |
| Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: |
| Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: |
| Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: | Date:  No Falls  Near Falls:  Falls: |

## Section C: Clinical Events - Cramps

We would like you to keep a diary about any cramps that you might have. Please mark the appropriate box or boxes every day to indicate when you have or have not had any cramps. Please record the number of cramps you experience in the space provided on the daily calendar and a global rating for the severity of cramps experienced over the period.

Clinical Events Cramps Data Collection Grid

| Sunday | Monday | Tuesday | Wednesday | Thursday | Friday | Saturday |
| --- | --- | --- | --- | --- | --- | --- |
| Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: |
| Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: |
| Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: |
| Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: |
| Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: | Date:  No Cramps  Cramps: |

Global rating of cramp severity over the period:

4 = Activity interrupted by severe cramps

3 = More than one cramp per day, or seven per week

2 = Spontaneous cramps one to seven times weekly

1 = Rare cramps, related to voluntary muscle activity

0 = None

## General Instructions

This form contains data elements that assess muscle strength of the participant/subject.

## Specific Instructions

*Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.*

* Section A: Clinical Milestones and Events – For each clinical event or milestone indicate whether it occurred and if applicable the date(s) it occurred
* Section B: Clinical Events – Falls – The date will be recorded as a 3-part date in the database (mm/dd/yyyy). If a near fall or falls is checked, indicate the number.
* Section C: Clinical Events - Cramps – The date will be recorded as a 3-part date in the database (mm/dd/yyyy). If cramps, indicate the number.